

K081676

JUL - 2 2008

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1. Submitter's Information: 21 CFR 807.92(a)(1)**

MEDISON CO., LTD.  
1003, Daechi-dong, Gangnam-gu,  
Seoul 135-280, Korea

**Contact Person:**

Mr. Kyung-Am, Shim  
Regulatory Affairs Manager

Telephone: 82.2.2194.1381  
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Email: kashim@medison.com

**Data Prepared:** May 15, 2008

**2. Name of the device:**Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

SONOACE X6 Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

**3. Identification of the predicate or legally marketed device:**

K043455, 12/21/2004, SA8000 SE Diagnostic Ultrasound System  
K063580, 12/14/2006, SONOACE X8 Diagnostic Ultrasound System

**4. Device Description:**

The SONOACE X6 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, color Doppler imaging, power Doppler imaging, PW/CW spectral Doppler mode, Harmonic imaging, Freehand 3D imaging mode or as a combination of these modes on the LCD display.

The SONOACE X6 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. The system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals.

The SONOACE X6 has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD 2-2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3-2004 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993, Biocompatibility

#### **5. Intended Uses:**

The SONOACE X6 system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include:

General, Gynecology, Abdomen, OB, Renal, Urology, Vascular, Small Part, Fetal Heart, Breast, Musculoskeletal, Pediatric, Cardiac, TCD, Neonatal applications.

#### **6. Technological Characteristics:**

The SONOACE X6 is substantially equivalent to the SA8000 SE Diagnostic Ultrasound System, cleared via K043455, and the SONOACE X8 Diagnostic Ultrasound System, cleared via K063580. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

**END of 510(K) Summary**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medison Co., Ltd.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

JUL - 2 2008

Re: K081676  
Trade/Device Name: SONOACE X6 Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: June 16, 2008  
Received: June 17, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE X6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C3-7EP  
C4-9ED  
NER4-9ES  
NEV4-9ES  
HL5-12ED  
L5-12/50EP

P2-4AH

CW 2.0

CW 4.0

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850


This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,



 Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

## Section 4.3 INDICATIONS FOR USE

## DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:

Device Name: SONOACE X6 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	N	N	N	N	N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N	N	N	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note 1	Note 2,4,5,6,7,8
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2,5,6,8
	Neonatal Cephalic	N	N	N	N	N	Note 1	
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 3, 7, 8
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 3, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2,5,6,8
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2,5,6,8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note 1	Note 5, 6
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C3-7EP for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C4-9ED for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 8
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676



## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: NER4-9ES for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

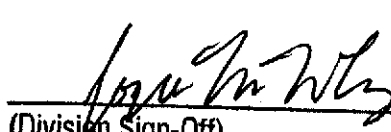
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)
Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081626

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: NEV4-9ES for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

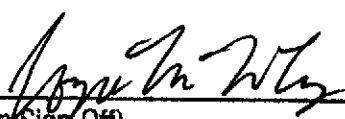
Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal and  
 Radiological Devices  
 510(k) Number K081626

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: HL5-12ED for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients


Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)
Division of Reproductive, Abdominal and  
Radiological Devices510(k) Number K081676

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT****510(k) No.:****Device Name:** L5-12/50EP for use with SONOACE X6**Intended Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)

 Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number

K081676

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: **P2-4AH for use with SONOACE X6**Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development


Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

**Concurrence of CDRH, Office of Device Evaluation (ODE)****Prescription Use (Per 21 CFR 801.109)**
  
 (Division Sign-Off)
Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW 2.0 for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW 4.0 for use with SONOACE X6

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric				P			
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared under K063580; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW, B/Color, B/PD, B/Color/PW, B/PD/PW, B/Color/Color M, B/Color/Steered CW, B/Steered CW

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Harmonic Imaging

Note 8: 3D imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081676